

### **REMARKS**

Applicant hereby requests further consideration of the application in view of the amendments above and the comments that follow.

The specification is amended herein as required to delete the language objected to in the Office Action on Page 2.

Claims 1, 2, 7-11, 17-19, 47-54 and 58-67 are pending in the present application. Claims 1, 2, 7-11, 17-19, 47-54 and 58-67 are canceled herein, without prejudice or disclaimer of the subject matter contained therein, in favor of new claims 68-73.

Claims 68-73 are added herein to complete the record. Support for new claims 68-73 can be found throughout the application as filed, for example:

- improving myocardial function: page 11, lines 9-11
- human subjects: page 3, lines 32-33
- myocardial ischemia: page 4, lines 2-6
- polyclonal, monoclonal or humanized antibody: page 4, lines 10-12
- SEQ ID NO:6 (DAFPGEPDKELNP): page 13, lines 7-13
- inhibiting EMAP II anti-angiogenic effect: page 11, lines 28 and 29.

Applicant believes that no new matter is added by new claim 68-73, and their entry and examination are respectfully requested.

### **Interview Summary**

Applicant would like to thank Examiner Phuong N. Huynh for her kind assistance in the phone interview conducted on August 20, 2008, with Applicant's representatives, Shawna Cannon Lemon and Sherry L. Murphy. The outstanding rejections issued in the present Office Action were discussed, including issues of new matter and enablement. No agreement was reached.

In light of the helpful and constructive dialog provided by the Examiner, Applicant herein provides amendments and remarks to expedite the prosecution of this application.

### **Objections to the Claims and Specification**

A. Claims 1, 11 and 58 are objected because of the abbreviation EMAP II appearing in the claims. Claims 1, 11 and 58 are canceled herein, rendering this objection moot. New

claims 68-73 recite Endothelial Monocyte Activating Polypeptide II (EMAP II) when first appearing in the claims. Therefore the withdrawal of this objection is respectfully requested.

**B.** The amendment filed by Applicant on May 9, 2008, is objected to under 35 U.S.C. § 132(a) for allegedly introducing new matter into the disclosure by stating: "Since the N-terminal sequence obtained from the purified EMAP II is encoded by an internal sequence of the EMAP II clone, it was predicted that mature EMAP II (e.g., SEQ ID NO:5) results from processing from a larger polypeptide (e.g., SEQ ID NO:4) (see Stern et al., U.S. Patent No. 5,641,867, incorporated by reference herein) as well as the Sequence Listing of SEQ ID NO:4 and SEQ ID NO:5."

Applicant notes that this text is from Stern et al., U.S. Patent No. 5,641,867, "Antibody Which Specifically Binds to Endothelial-monocyte Activating Polypeptide II," which disclosure is specifically incorporated by reference in the application as filed (see page 4, lines 17-18), and, therefore, contains no new matter. As noted on page 7 of Applicant's response filed May 9, 2008, support for SEQ ID NO:5 and the text added to the paragraph on page 5, lines 15-23, may be found in Figure 4A-4D and column 29, lines 28-31, of Stern et al. See 37 C.F.R. § 1.57(f). As noted in M.P.E.P. § 2163.07(b):

The information incorporated is as most a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter.

The case law is consistent with this interpretation. Incorporation by reference can be used to find a reference anticipatory based, in part, upon the disclosures so incorporated. See *Ultradent Products Inc. v. Life-Like Cosmetics Inc.*, 44 USPQ2d 1336, 1339 (Fed. Cir. 1997) ("The error in the district court's summary judgment order related to the nature of the disclosure in the prior art. The Munro patent incorporated by reference the entire contents of the Rosenthal disclosure. Ultradent's assertion that Munro 'says nothing' about the Rosenthal compositions and merely discloses using the commercial embodiment of the Rosenthal patent is contrary to the rules of practice, which permit incorporation of prior art by reference [citing to the M.P.E.P.]."). Incorporation by reference also carries the danger that a claim term will be interpreted based upon the disclosures found in the reference so incorporated. See *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1376 (Fed. Cir. 2006) (defining the claim term

“urinary bladder submucosa” by the descriptions provided in a patent incorporated by reference, which was considered to be included in the specification, and in so doing found non-infringement of the asserted claims).

Nonetheless, in order to expedite the prosecution of this application, Applicant has deleted this text from the specification as required by the Office Action. In view thereof, Applicant respectfully requests that the objection be withdrawn.

### **Section 112, First Paragraph Rejections**

A. Claims 1-4, 6-14, 16-19 and 47-54 stand rejected under 35 U.S.C. § 112, first paragraph, enablement. Applicant has canceled claim 1-4, 6-14, 16-19 and 47-54, in favor of new claims 68-73, which follow the language indicated to be enabled in the Office Action on Page 4. In view thereof, Applicant respectfully requests the withdrawal of this rejection.

B. Claims 1-2, 7-11, 17-19, 47-54 and 58-67 are rejected under 35 U.S.C. § 112, first paragraph, as containing new matter. Claims 1-2, 7-11, 17-19, 47-54 and 58-67 are canceled herein, rendering this rejection moot. In view thereof, Applicant respectfully requests the withdrawal of this rejection.

New claims 68-73 are supported by the application as filed. For example, the recitation of a “human subject” is found at page 3, lines 32-33: “While subjects treated by the present invention are primarily human subjects, the invention may also be carried out on other animal subjects such as dogs, cats, horses, etc. for veterinary purposes.”

SEQ ID NO:6 (DAFPGEPPDKELNP) consists of SEQ ID NO:1 without the N-terminal cysteine residue, which cysteine residue is specifically stated in the application as filed on page 13, lines 12-14, to be assigned for use in the single point, site-directed conjugation procedure described for generation of the monoclonal antibody, and is not included in the EMAP II epitope.

C. Claims 1-2, 7-11, 17-19, 47-54 and 58-67 are rejected under 35 U.S.C. § 112, first paragraph, written description. Claims 1-2, 7-11, 17-19, 47-54 and 58-67 are canceled herein, rendering this rejection moot. In view thereof, Applicant respectfully requests the withdrawal of this rejection.

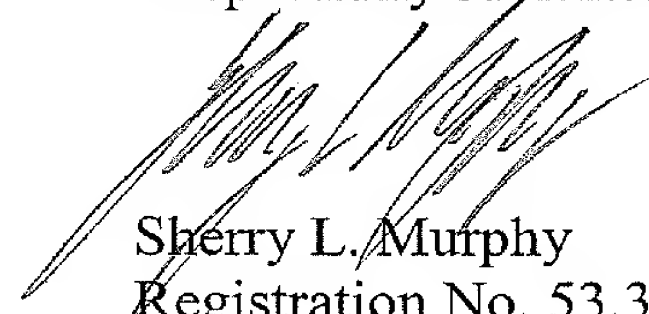
New claims 68-73 recite a method of improving myocardial function of a subject in need of such treatment, the method comprising administering an antibody that binds to an epitope of Endothelial Monocyte Activating Polypeptide II (EMAP II), wherein the epitope consists of the amino acid sequence of SEQ ID NO:6, in an amount sufficient to inhibit the anti-angiogenic activity of EMAP II in the subject, thereby improving myocardial function in the subject.

Given this focus of new claims 68-73, which do not recite facilitating vascular growth in cardiac muscle or the promotion of blood vessel formation, nor binding to EMAP II of SEQ ID NO: 4 or 5, Applicant believes that new claims 68-73 are adequately described in the specification as filed. However, if the Examiner finds that the amendments do not overcome this rejection under § 112, Applicant solicits the Examiner's suggestions as to satisfactory amendment.

#### CONCLUSION

In view of the amendments and remarks set forth above, Applicant respectfully submits that the present application is in condition for allowance, and the same is earnestly solicited. Should the Examiner have any small matters outstanding of resolution, she is invited and encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,



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